

**WHAT IS CLAIMED IS:**

1        1. A composition comprising a haptenized tumor cell or tumor cell extract  
2 comprising from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or cell equivalents per dose, wherein  
3 the tumor cells or cell equivalents are conjugated to a hapten and rendered incapable of growth or  
4 multiplication *in vivo*.

1        2. The composition of claim 1, wherein the hapten is selected from the group  
2 consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene  
3 diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene  
4 isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations  
thereof.

1        3. The composition of claim 2, in which the hapten is dinitrophenyl.

1        4. The composition of claim 1, wherein the tumor cell extract comprises tumor cell  
2 membrane components.

1        5. The composition of claim 1, wherein the tumor cell extract comprises tumor cell  
2 polypeptides.

1        6. The composition of claim 1, wherein the tumor cells or tumor cell extracts  
2 originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon  
3 cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

1        7. The composition of claim 6, wherein the tumor is melanoma.

1        8. The composition of claim 6, wherein the tumor is ovarian cancer.

1           9.     The composition of claim 1, wherein the tumor cell or tumor cell extract has been  
2     rendered incapable of growth by irradiation.

1           10.    The composition of claim 1, free of any adjuvant.

1           11.    A method for inducing an anti-tumor response in a mammalian patient suffering  
2     from a tumor, which method comprises administering to the patient a composition comprising a  
3     haptenized tumor cell or tumor cell extract comprising from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor  
4     cells or cell equivalents per dose, wherein the tumor cells or cell equivalents are conjugated to a  
5     hapten, and rendered incapable of growth or multiplication *in vivo*.

1           ✓ 12.   The method of claim 10, which further comprises administering a first dose of the  
2     composition without any adjuvant.

1           ✓ 13.   The method of claim 10, wherein the composition is administered prior to a  
2     second composition comprising an adjuvant and a tumor cell or tumor cell extract, which second  
3     composition

- 4           a) is conjugated to a hapten, and  
5           b) contains from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or tumor cell equivalents.  
*B1*

1           ✓ 14.   The method of claim 13, wherein the adjuvant is selected from the group  
2     consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

1           15.    The method of claim 11, wherein the composition is administered prior to the  
2     administration of cyclophosphamide.

1           ✓ 16.   The method of claim 14, wherein the composition is administered four to seven  
2     days prior to the administration of cyclophosphamide.  
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1           17. The method of claim 10, wherein the tumor cells or tumor cell extracts originate  
2 from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer,  
3 breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

*M*  
1           18. The method of claim 10, wherein the tumor cells or tumor cell extracts are  
2 autologous.

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1           19. The method of claim 10, wherein the tumor is melanoma.

1           20. The method of claim 10, wherein the patient is a human.

1           21. A method for inducing an anti-tumor response in a mammalian patient  
2 suffering from a tumor, which method comprises administering to the patient:  
3           (a) on the first day of the treatment, a composition comprising autologous tumor cells or  
4 tumor cell extracts, which corresponds to from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells, free of  
5 any adjuvant;  
6           (b) four to seven days after initiation of the treatment, an immunomodulatory agent that  
7 potentiates protective anti-tumor immunity or inhibits immune suppression, or both; and  
8           (c) at least one additional composition comprising autologous tumor cells or tumor cell  
9 extracts.

1           22. The method of claim 21, in which the immunomodulatory compound is  
2 cyclophosphamide.

1           23. A method for inducing an anti-tumor response in a mammalian patient  
2 suffering from a tumor, which method comprises administering to the patient:  
3           (a) on the first day of the treatment, a composition comprising a haptenized autologous  
4 tumor cell or tumor cell extract which corresponds to from about  $2 \times 10^5$  to  $2.5 \times 10^6$  tumor cells  
5 free from any adjuvant;

1           (b) four to seven days after initiation of the treatment, cyclophosphamide; and  
2           (c) at least one week after initiation of the treatment, a composition comprising an  
3       adjuvant and a haptенized autologous tumor cell or tumor cell extract which corresponds to from  
4       about  $2 \times 10^5$  to about  $1 \times 10^7$  tumor cells.

1           24.      The method in claim 22, in which the adjuvant is *Bacille Calmette-Guerin*.

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